

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-76 (Canceled)

Claim 77 (Currently Amended): A nucleic acid/lipid/~~polycationic polypeptide salt~~ protamine salt complex comprising a nucleic acid, at least one lipid species, and at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt in a ratio such that the complex has a positive charge excess of lipid and ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt to nucleic acid, ~~[[and]]~~ wherein the complex further comprises a targeting factor directed to a cell surface molecule, and wherein the diameter of the stored complex does not increase by more than 100% over the diameter of the complex as determined at the time the complex was purified, after 4 months in storage in 5% dextrose.

Claims 78-82 (Canceled)

Claim 83 (Currently Amended): The complex of claim ~~[[81]]~~ 77, wherein the surface of the complex is positively charged.

Claim 84 (Currently Amended): The complex of claim 77, wherein the at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt is a sulfate salt.

Claims 85-87 (Canceled)

Claim 88 (Previously Presented): The complex of claim 77, wherein the nucleic acid comprises an E1A gene.

Claim 89 (Previously Presented): The complex of claim 77, wherein the at least one lipid is a cationic lipid.

Claim 90 (Previously Presented): The complex of claim 77, wherein the at least one lipid is 3 $\beta$ [N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

Claim 91 (Currently Amended): The complex of claim 77, wherein the at least one ~~polypeptide~~ protamine sulfate or chloride salt is from about 20 to about 100 amino acids in length.

Claim 92 (Previously Presented): The complex of claim 77, wherein the complex further comprises a neutral phospholipid species.

Claim 93 (Currently Amended): The complex of claim 77, wherein the ratio of the nucleic acid:lipid:~~polycationic polypeptide salt~~ protamine sulfate or chloride salt is about 1 µg/0.1 nmol/0.01 µg to about 1 µg/200 nmol/100 µg.

Claim 94 (Previously Presented): The complex of claim 77, wherein the complex has a diameter of less than about 400 nm.

Claim 95 (Currently Amended): A nucleic acid/lipid/~~polycationic polypeptide salt~~ protamine salt complex comprising a nucleic acid, at least one lipid species, and at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt, wherein the complex further comprises a targeting factor directed to a cell surface molecule, and ~~[[,]]~~ wherein the complex is shielded.

Claim 96 (Canceled)

Claim 97 (Currently Amended): The complex of claim 95, ~~further comprising a~~ wherein the complex comprises a compound comprising polyethylene glycol moieties.

Claim 98 (Currently Amended): A method for producing a nucleic acid/lipid/~~polycationic polypeptide salt~~ protamine salt complex of claim 77, the method comprising combining the nucleic acid, the lipid, the ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt, and the targeting factor to form the complex.

Claim 99 (Currently Amended): The method of claim 98, wherein the nucleic acid, lipid, and ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt are mixed in a ratio of about 1 µg/0.1 nmol/0.01 µg to 1 µg/200 nmol/100 µg.

Claim 100 (Previously Presented): The method of claim 98, wherein the at least one lipid is a cationic lipid.

Claim 101 (Previously Presented): The method of claim 100, wherein the at least one cationic lipid is  $3\beta$ [N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

Claim 102 (Canceled)

Claim 103 (Currently Amended): The method of claim 98, wherein the at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt is a protamine sulfate salt.

Claim 104 (Previously Presented): A method for delivering nucleic acid to cells comprising contacting the cells with the complex of claim 77.

Claim 105 (Previously Presented): The method of claim 104, wherein the cells are contacted with the complex *in vivo*, the method comprising administering the complex to an individual in an amount effective to deliver the nucleic acid into the cells of the individual.

Claim 106 (Currently Amended): The method of claim 105, wherein the at least one lipid is  $3\beta$ [N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol), and the at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt is a protamine sulfate salt.

Claim 107 (Previously Presented): The complex of claim 77, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 108 (Previously Presented): The complex of claim 77, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 109 (Previously Presented): The complex of claim 77, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 110 (Currently Amended): The complex of claim [[81]] 90, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 111 (Currently Amended): The complex of claim [[81]] 90, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 112 (Currently Amended): The complex of claim [[81]] 90, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 113 (Currently Amended): ~~A method of delivering a nucleic acid to an individual, the method comprising administering to the individual a nucleic acid/lipid/polycationic polypeptide salt complex comprising a nucleic acid, at least one lipid species, and at least one polycationic polypeptide salt;~~ The method of claim 105, wherein the complex is administered intratumorally, intravenously, intratracheally, intraperitoneally or intramuscularly.

Claim 114 (Currently Amended): The method of claim 113, wherein the complex is administered ~~intravenously~~ intravenously.

Claim 115 (Previously Presented): The method of claim 113, wherein the complex is administered as an aerosol or liquid solution.

Claim 116 (Canceled)

Claim 117 (Previously Presented): The method of claim 113, and wherein the surface of the complex is positively charged.

Claims 118-121 (Canceled)

Claim 122 (Currently Amended): The method of claim 113, wherein the at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt is a sulfate salt.

Claims 123 and 124 (Canceled)

Claim 125 (Previously Presented): The method of claim 113, wherein the nucleic acid comprises an E1A gene.

Claim 126 (Previously Presented): The method of claim 113, wherein the at least one lipid is a cationic lipid.

Claim 127 (Previously Presented): The method of claim 113, wherein the at least one lipid is 3 $\beta$ [N-(N', N'-dimethylaminoethane)-carbamoyl]cholesterol (DC-Chol).

Claim 128 (Currently Amended): The method of claim 113, wherein the at least one ~~polypeptide~~ protamine sulfate or chloride salt is from about 20 to about 100 amino acids in length.

Claim 129 (Previously Presented): The method of claim 113, wherein the complex further comprises a neutral phospholipid species.

Claim 130 (Previously Presented): The method of claim 113, wherein the complex has a diameter of less than about 400 nm.

Claim 131 (Previously Presented): The method of claim 113, wherein the complex is shielded.

Claim 132 (Canceled)

Claim 133 (Previously Presented): The method of claim 113, wherein the complex further comprises a compound comprising polyethylene glycol moieties.

Claim 134 (Currently Amended): The method of claim 113, wherein the nucleic acid, lipid, and ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt are present in a ratio of about 1  $\mu$ g/0.1 nmol/0.01  $\mu$ g to 1  $\mu$ g/200 nmol/100  $\mu$ g.

Claims 135 and 136 (Canceled)

Claim 137 (Previously Presented): The method of claim 98, wherein the complex is shielded.

Claim 138 (Previously Presented): The method of claim 98, wherein the complex further comprises a compound comprising polyethylene glycol moieties.

Claim 139 (Previously Presented): The method of claim 98, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 140 (Previously Presented): The method of claim 98, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 141 (Previously Presented): The method of claim 98, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 142 (Previously Presented): The method of claim 104, wherein the complex is shielded.

Claim 143 (Previously Presented): The method of claim 104, wherein the complex further comprises a compound comprising polyethylene glycol moieties.

Claim 144 (Previously Presented): The method of claim 104, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 145 (Previously Presented): The method of claim 104, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 146 (Previously Presented): The method of claim 104, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 147 (Canceled)

Claim 148 (Currently Amended): The method of claim [[147]] 113, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 149 (Currently Amended): The method of claim [[147]] 113, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 150 (Currently Amended): The method of claim [[147]] 113, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 151 (Currently Amended): The method of claim [[136]] 122, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 152 (Currently Amended): The method of claim [[136]] 122, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 153 (Currently Amended): The method of claim [[136]] 122, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 154 (Previously Presented): The complex of claim 107, wherein the complex is shielded.

Claim 155 (Previously Presented): The complex of claim 107, wherein the complex further comprises a compound comprising polyethylene glycol moieties.

Claim 156 (Currently Amended): A nucleic acid/lipid/~~polycationic polypeptide salt~~ protamine salt complex comprising a nucleic acid, at least one lipid species, and at least one

~~polycationic polypeptide salt~~ protamine sulfate or chloride salt in a ratio such that the complex has a positive charge excess of lipid and ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt to nucleic acid, and wherein the complex further comprises a targeting factor directed to a cell surface molecule, and wherein the average diameter of the complex ~~has a diameter of~~ is less than about ~~[[400]]~~ 200 nm.

Claims 157 and 158 (Canceled)

Claim 159 (Currently Amended): The complex of claim ~~[[158]]~~ 156, wherein the surface of the complex is positively charged.

Claim 160 (Currently Amended): The complex of claim 156, wherein the at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt is a sulfate salt.

Claims 161 and 162 (Canceled)

Claim 163 (Previously Presented): The complex of claim 156, wherein the nucleic acid comprises an E1A gene.

Claim 164 (Previously Presented): The complex of claim 156, wherein the at least one lipid is a cationic lipid.

Claim 165 (Previously Presented): The complex of claim 156, wherein the at least one lipid is 3β[N-(N', N'-dimethylaminoethane)-carbonyl]cholesterol (DC-Chol).

Claim 166 (Currently Amended): The complex of claim 156, wherein the at least one ~~polypeptide~~ protamine sulfate or chloride salt is from about 20 to about 100 amino acids in length.

Claim 167 (Previously Presented): The complex of claim 156, wherein the complex further comprises a neutral phospholipid species.

Claim 168 (Currently Amended): The complex of claim 156, wherein the ratio of the nucleic acid:lipid:~~polycationic polypeptide salt~~ protamine sulfate or chloride salt is about 1 μg/0.1 nmol/0.01 μg to about 1 μg/200 nmol/100 μg.



Claim 169 (Canceled)

Claim 170 (Currently Amended): A nucleic acid/lipid/~~polycationic polypeptide salt~~ protamine salt complex comprising a nucleic acid, at least one cationic lipid species, at least one neutral lipid species, and at least one ~~polycationic polypeptide salt~~ protamine sulfate or chloride salt, wherein the complex further comprises a targeting factor directed to a cell surface molecule, and [[,]] wherein the complex is shielded.

Claim 171 (Currently Amended): The complex of claim 170, ~~further comprising~~ wherein the complex comprises a compound comprising polyethylene glycol moieties.

Claim 172 (Previously Presented): The complex of claim 156, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 173 (Previously Presented): The complex of claim 156, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 174 (Previously Presented): The complex of claim 156, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 175 (Currently Amended): The complex of claim ~~[[158]]~~ 167, wherein the targeting factor is selected from the group consisting of modified lipids, proteins, polycations and receptor ligands.

Claim 176 (Currently Amended): The complex of claim ~~[[158]]~~ 167, wherein the targeting factor is selected from the group consisting of asialoglycoprotein, insulin, low density lipoprotein (LDL), folate, monoclonal antibodies and polyclonal antibodies.

Claim 177 (Currently Amended): The complex of claim ~~[[158]]~~ 167, wherein the targeting factor is directed to a cell type selected from the group consisting of liver, blood, endothelial and tumor cells.

Claim 178 (New): The complex of claim 77, wherein the complex has a diameter of less than about 200 nm.

Claim 179 (New): The complex of claim 95, wherein the complex has a diameter of less than about 400 nm.

Claim 180 (New): The complex of claim 95, wherein the complex has a diameter of less than about 200 nm.

Claim 181 (New): The complex of claim 95, wherein the at least one protamine sulfate or chloride salt is a sulfate salt.

Claim 182 (New): The complex of claim 95, wherein the diameter of the stored complex does not increase by more than 100% over the diameter of the complex as determined at the time the complex was purified, after 4 months in storage in 5% dextrose.

Claim 183 (New): The method of claim 98, wherein the complex has a diameter of less than about 400 nm.

Claim 184 (New): The method of claim 98, wherein the complex has a diameter of less than about 200 nm.

Claim 185 (New): The method of claim 98, wherein the diameter of the stored complex does not increase by more than 100% over the diameter of the complex as determined at the time the complex was purified, after 4 months in storage in 5% dextrose.

Claim 186 (New): The method of claim 105, wherein the complex has a diameter of less than about 200 nm.

Claim 187 (New): The complex of claim 156, wherein the complex further comprises a compound comprising polyethylene glycol moieties.

Claim 188 (New): The complex of claim 156, wherein the diameter of the stored complex does not increase by more than 100% over the diameter of the complex as determined at the time the complex was purified, after 4 months in storage in 5% dextrose.

Claim 189 (New): The complex of claim 170, wherein the complex has a diameter of less than about 400 nm.

Claim 190 (New): The complex of claim 170, wherein the complex has a diameter of less than about 200 nm.

Claim 191 (New): The complex of claim 170, wherein the diameter of the stored complex does not increase by more than 100% over the diameter of the complex as determined at the time the complex was purified, after 4 months in storage in 5% dextrose.